



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

**NOTICE OF ALLOWANCE AND ISSUE FEE DUE**

002052 HM22/1024  
OSTROLENNYK, PAUL, SERB & SOFFEN  
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NEW YORK NY 10036-8403

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
09/500,009	02/08/00	012	SCHNIZER, H	1653 10/24/00
First Named Applicant	MEHTA, 35 USC 154(b) term ext. = 0 Days.			

TITLE OF INVENTION: DIRECT EXPRESSION OF PEPTIDES INTO CULTURE MEDIA

ATTYS DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
1 P/546-221 D1	435-069.100	U14	UTILITY	YES	\$620.00	01/24/01

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.**

**THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.**

**HOW TO RESPOND TO THIS NOTICE:**

**I. Review the SMALL ENTITY status shown above.**

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

If the SMALL ENTITY is shown as NO:

- A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
- B. If the status is the same, pay the FEE DUE shown above.

A. Pay FEE DUE shown above, or

B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give application number and batch number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

***IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.***

**PATENT AND TRADEMARK OFFICE COPY**

## Notice of Allowability

Application No.

09/500,009

Applicant(s)

Mehta et al.

Examiner

Holly Schnizer

Group Art Unit

1653



All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.

☒ This communication is responsive to the response filed October 10, 2000

☒ The allowed claim(s) is/are 16-19, 21, 28-31, 39, 71, and 74

☐ The drawings filed on \_\_\_\_\_ are acceptable.

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE **THREE MONTHS** FROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.

☒ Applicant MUST submit NEW FORMAL DRAWINGS

☐ because the originally filed drawings were declared by applicant to be informal.

☒ including changes required by the Notice of Draftsperson's Patent Drawing Review, PTO-948, attached hereto or to Paper No. 4

☐ including changes required by the proposed drawing correction filed on \_\_\_\_\_, which has been approved by the examiner.

☐ including changes required by the attached Examiner's Amendment/Comment.

**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.**

☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any response to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

### Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☐ Interview Summary, PTO-413

☐ Examiner's Amendment/Comment

☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

☒ Examiner's Statement of Reasons for Allowance

Art Unit: 1653

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 16-19, 21, 28-31, 39, 71, and 74 are pending.

### ***Drawings***

2. Applicant is reminded that the drawings filed February 8, 2000 are objected to because of the defects noted on Form PTO 948 which was attached to the previous Office Action (Paper No. 4, mailed 6/7/00). Correction is required.

### ***Reasons for Allowance***

3. The following is an examiner's statement of reasons for allowance:
4. Claims 16-19, 21, 28-31, 39, 71, and 74 are allowable. Claim 16 has been amended to include the limitation that the vector comprises a plurality of transcription cassettes. Thus, Claim 16 and dependent Claims 17-19 are now drawn to vectors containing more than one expression cassette wherein each expression cassette has a control region containing a plurality of promoters. The closest related art found was that of Ying and Shengdong (Chin. Med. Sci. J. (1996) 11(1): 204-208, cited in IDS (Paper No. 2)) who teach that a tandem repeating expression cartridge containing a control region and coding region provides a convenient means to improve expression efficiently. However, each of the tandemly repeated expression cassettes of the Ying and

Art Unit: 1653

Shengdong reference only contained one promoter and not a plurality of promoters as claimed in the present invention. Moreover, the Ying and Shengdong reference does not suggest adding a nucleic acid sequence coding for a secretion enhancing peptide to the vectors taught therein.

Since the vectors appear to be allowable over the prior art, it follows that host cells containing these vectors (Claims 21 and 28-31) and methods of making proteins (Claims 39, 71, and 74) using these vectors and host cells would also be allowable over the prior art.

5. It is noted that Claims 16-19, 21, 28-31, 39, 71, and 74 of the present application are encompassed by Claim 1 in related Application No. 09/060,765, now U. S. Patent No. 6103495. However, double patenting does not apply in the present application since the claims conform to the Restriction Requirement given in parent Application number 09/060,765 ( Paper No. 13, mailed 4/26/99).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Art Unit: 1653

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (703) 305-3722. The examiner can normally be reached Monday and Thursday from 8:00 a.m. to 5:30 p.m. and Tuesday and Wednesday from 9:00 a.m. to 2:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 306-4119. The fax phone number for Official Papers to this Group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Holly Schnizer, Ph.D.  
October 19, 2000



KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER